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HL

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/896,821 07/18/97 QUAY

S SNUS125

HM12/0621

W. PATRICK BENGTSOON
LIMBACH AND LIMBACH
2001 FERRY BUILDING
SAN FRANCISCO CA 94111

EXAMINER

HOLLINDEN, G

ART UNIT	PAPER NUMBER
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1616

14

DATE MAILED:

06/21/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/25/99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 15-35 is/are pending in the application.

Of the above, claim(s) 15-29, 32-35 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 30 & 31 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

This Office Action is a response to the amendment filed on March 25, 1999 wherein claim 35 was added and claims 32-34 were amended. Currently, Claims 15-35 are pending in this application. Claims 15-29 remain withdrawn as not reading the elected species currently being prosecuted.

Applicant's remarks¹ regarding the discussion of dependent claims 32-34 are noted. Examiner concurs that it is clear that in the Office Action dated September 22, 1998 claims 32-34 were taken to mean that they were dependent on claim 31 i.e. that the compositions set forth therein contained human protein and the additional excipients set forth therein and were thus examined as if they also contained human protein. As Applicant correctly noted, such is not the case. Therefore claims 32-35² are not actually a part of the elected species being examined and are hereby withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected species. In addition, Examiner concurs that the Election of Species is made solely for purposes of examination of the application and at the time that the instant species becomes allowable, the additional species would be examined.

The Applicant's response in the amendment filed on March 25, 1999 to the rejection made by the Examiner under 35 U.S.C. § 112 second paragraph fully meet the deficiencies encompassed by said rejection. Therefore, said rejection is hereby withdrawn.

The Applicant's response in the amendment filed on March 25, 1999 to the rejection made by the Examiner under 35 U.S.C. § 103 fully meet the deficiencies encompassed by said rejection. Therefore, said rejection is hereby withdrawn.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

¹found in the third paragraph of page 3.

²claim 35 is also being withdrawn because it also does not contain human protein since it depends from claim 33. It is noted that at the time 35 would be examined it would be rejected because it does not appear to further limit claim 33 because claim 33 (since it depends from claim 30) is already limited to gases which include perfluoropropane.

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 30³ and 31 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time that application was filed, had possession of the claimed invention for reasons of record stated in the Office Action dated September 22, 1998.

Applicant's arguments filed on March 25, 1999 have been fully considered but they are not deemed to be persuasive for the following reasons:

1) Applicant asserts that the specification need not describe the invention in the same exact words in order to meet the description requirement and further assert that every nuance of the claims need not be specifically described. However, the instant issue is not whether specific words or phrase had been used but whether specific compositions had been adequately described so as to show possession thereof. It has been well established that simply because a specification teaches a genus that would include a particular species, the specification does not provide written description for all the species listed therein. *In re Ruschig*⁴ states:

"Disclosure such as that found in formula and words of claim does not amount to a disclosure, sufficient to support a specific claim, of every compound a skilled chemist can see is within scope of that claim; specific claims to single compounds require reasonably specific supporting disclosure; while naming is not essential, something more than disclosure of a class of 1000, 100, or even 48 compounds is required; given time, a chemist could name all of the half million compounds within scope of broadest claim, which claim is supported by broad disclosure; this does not constitute support for each compound individually when separately claimed."

"It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail ... to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none."

³Applicant correctly notes that claim 30 is not limited to human protein as the shell material. However, claim 30 is currently only being examined to the extent that it reads upon the elected species (§ 2 of the Office Action dated September 22, 1998) and as such, is limited to human protein for purposes of examination. As noted above, when the instant species becomes allowable, it will be fully examined.

⁴154 USPQ 118, CCPA 1967

In the instant case, Applicant did provide written description for perfluoropropane which is now claimed since they were named as part of a long list of specifically named compounds which would be useful in the invention. However, the instant claims are drawn to a composition wherein each gas is combined with a specific sub-genus of shell material. The claim designated shell material, human protein, was also described in the specification as part of a large number of additional adjuvants⁵ which may be used. Thus, to arrive at the claim designated invention, the artisan must pull a specific gas from one list and pair it with a specific shell material from another list. As stressed in *In re Winkhaus*:⁶

"That a person skilled in the art might realize from reading the disclosure that such a step is possible is not a sufficient indication to that person that that step is part of Apellants' invention. Such an indication is the least that is required for a description of the invention under the first paragraph of § 112."

As in *Winkhaus*, the pairing of the specific gas with a specific shell material might be seen in hindsight to be possible. However, there is no indication that these particular combinations were originally considered to be a part of Applicant's invention.

2) Applicant asserts that the instant claims merely require the selection of a specific gas and the formation of a microbubble using the existing techniques set forth in the specification; however, the selection of human protein is not the selection of an existing technique but rather the selection of a specific shell agent (human protein) from among the many possible adjuvant disclosed to be used in a specific technique (formation of microbubbles) from among a large number of disclosed techniques. Therefore, to arrive at the claim designated species one has to pair all three together. Again, as stated above, there was simply no indication in the original specification that Applicant intended to form this particular combination.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. § 112 first paragraph. Therefore, the rejection is adhered to.

⁵Depending on the technique discussed the adjuvant may be a shell material, a suspending agent, a crystal, etc.

⁶188 USPQ 129, CCPA 1975

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 30 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. patent nos. 5,409,688, 5,393,524, 5,573,751, 5,558,854, 5,558,094, 5,558,855, and 5,558,853 because the instant elected composition is drawn to a specific sub-genus which would be encompassed within the broader claims of the cited patents for reasons of record stated in the Office Action dated September 22, 1998.

Applicant's agreement to file an appropriate terminal disclaimer filed on March 25, 1999 is acknowledged.

Claims 30-and 31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending application serial no. 08/466,104, 08/646,910, 08/710,849, 08/770,522, 08/745,256, and 08/900,986. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant elected composition is drawn to a specific sub-genus which would be encompassed within the broader claims of the cited applications for reasons of record stated in the Office Action dated September 22, 1998.

Applicant's agreement to file an appropriate terminal disclaimer filed on March 25, 1999 is acknowledged.

The obviousness-type double patenting rejection, whether of the obviousness type or non-obviousness type, is based on a judicially created doctrine grounded in public policy (a

Art Unit 1616

policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent⁷.

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 30 and 31 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of the claims of copending application Serial No. 08/710,849. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented for reasons of record stated in the Office Action dated September 22, 1998.

Applicant's arguments filed on March 25, 1999 have been fully considered. Applicant is apparently making reference to the fact that if 08/710,849 is still pending when the instant claims become allowable, then this rejection should be withdrawn in this case and maintained in '849.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ...". Thus, the term "same invention," in this context means an invention drawn to identical subject matter⁸.

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are not longer coextensive in scope. The filing of terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

⁷*In re Thorington*, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 214 USPQ 761 (CCPA 1982); *In re Longi*, 225 USPQ 645 (CA FC 1985); and *In re Goodman*, 29 USPQ 2010 (CA FC 1993).

⁸*Miller v. Eagle Mfg.* 151 U.S. 186 (1894); *In re Ockert*, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 164 USPQ 619 (CCPA 1970).

Art Unit 1616

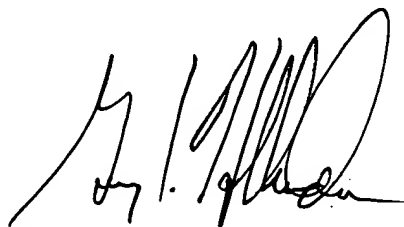
In view of the objections /rejections to the pending claims set forth above, no claims may be allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this Office Action or any earlier Office Actions in this application should be directed to Dr. Gary E. Hollinden whose telephone number is 703/308-4521. Dr. Hollinden's office hours are from 6:30 am to 3:00 pm, Monday through Friday.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703/308-1235.

A handwritten signature in black ink, appearing to read 'Gary E. Hollinden', is written over a horizontal line.

Gary E. Hollinden, Ph.D.
Primary Examiner
Group 1616